

ADULT LOW DOSE ASPIRIN- aspirin tablet, delayed release
Rising Pharma Holdings, Inc.

Compare to the active ingredient in Bayer® Low Dose Aspirin†

**Adult Low Dose
Aspirin
81 mg
Pain Reliever (NSAID)
adult aspirin regimen use
delayed release
safe pain relief
SEE NEW WARNINGS INFORMATION**

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts

<i>Active ingredient (in each tablet)</i>	<i>Purpose</i>
Aspirin 81 mg (NSAID)*.....	Pain reliever

*nonsteroidal anti-inflammatory drug

Uses

- temporary relief of minor aches and pains or as recommended by your doctor.
Because of its delayed release action, this product will not provide fast relief of headache or symptoms needing immediate relief.

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- hives
- shock
- facial swelling
- asthma (wheezing)

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding.

The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin,

ibuprofen, naproxen, or others]

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you are allergic to aspirin, or any other pain reliever/fever reducer

Ask a doctor before use if

- You have asthma
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout, or arthritis
- under a doctor's care for any serious condition
- taking any other drug

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - has bloody or black stools
 - vomits blood
 - has stomach pain that does not get better
- an allergic reaction occurs. Seek medical help right away.
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever get worse or lasts for more than 3 days
- redness or swelling is present in the painful area
- new symptoms appear. These could be sign of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- drink a full glass of water with each dose
- **adults and children 12 years and over:**
- take 4 to 8 tablets every 4 hours while symptoms last
- do not take more than 48 tablets in 24 hours unless directed by doctor
- **children under 12 years:** ask a doctor

Other information

- store at room temperature 15-30°C (59-86°F)

Inactive ingredients

Colloidal silicon dioxide, croscarmellose sodium, D&C yellow 10, iron oxide yellow 6, lactose, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polysorbate 80, sodium hydroxide, talc, titanium dioxide, triethyl citrate

Questions and comments? Call 1-844-474-7464

†This product is not manufactured or distributed by Bayer, owner of the registered trademark Aspirin Regimen BAYER®

Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Made in India

Mfg. Lic. No.: G/25/1362

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**Adult Low Dose****Aspirin****81 mg****NDC 57237-349-10****1,000 Tablets**

Rising NDC 57237-349-10

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Adult Low Dose Aspirin

81 mg

Pain Reliever (NSAID)

- adult aspirin regimen use
- delayed release
- safe pain relief

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1,000 Tablets

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Allergy alert: Aspirin may cause a severe allergic reaction, which may include:
 ■ hives ■ shock ■ facial swelling ■ asthma (wheezing)
Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed
Do not use ■ if you are allergic to aspirin, or any other pain reliever/fever reducer
Ask a doctor before use if ■ You have asthma ■ stomach bleeding warning applies to you ■ you have a history of stomach problems, such as: heartburn ■ you have high blood pressure, heart disease, liver cirrhosis or kidney disease ■ you are taking a diuretic
Ask a doctor or pharmacist before use if you are ■ taking a prescription drug for diabetes, gout, or arthritis ■ under a doctor's care for any serious condition ■ taking any other drug
Stop use and ask a doctor if
 ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ has bloody or black stools ■ vomits blood ■ has stomach pain that does not get better ■ an allergic reaction occurs. Seek medical help right away.

Drug Facts (continue)
 ■ ringing in the ears or loss of hearing occurs ■ pain gets worse or lasts for more than 10 days ■ fever get worse or lasts for more than 3 days ■ redness or swelling is present in the painful area ■ new symptoms appear. These could be sign of a serious condition.
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Other information
 ■ store at room temperature 15-30°C (59-86°F)
Inactive ingredients: Colloidal silicon dioxide, croscarmellose sodium, D&C yellow 10, iron oxide yellow 6, lactose, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polysorbate 80, sodium hydroxide, talc, titanium dioxide, triethyl citrate
Questions and comments? Call 1-844-474-7464



Unvarnish Area
50x30 mm

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 Distributed by:
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 East Brunswick, NJ 08816
 Made in India
 Mfg. Lic. No.: G/25/1362
 Revised: 10/2025
 S-071-01

ADULT LOW DOSE ASPIRIN

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-349
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ACETYLSALICYLIC ACID - UNII:R16CO5Y76E)		ASPIRIN	81 mg

Inactive Ingredients		Strength
Ingredient Name		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)		
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
sodium hydroxide (UNII: 55X04QC32I)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		

Product Characteristics			
Color	yellow	Score	no score

Shape	ROUND	Size	7mm
Flavor		Imprint Code	81
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-349-12	120 in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2025	
2	NDC:57237-349-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/09/2025	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Registrant - Elysium Pharmaceuticals Ltd (915664486)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		915664486	manufacture(57237-349) , analysis(57237-349)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		863182240	label(57237-349) , pack(57237-349)

Revised: 11/2025

Rising Pharma Holdings, Inc.